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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,098	02/26/2002	Arthur D. Gershowitz	032722-594	8586
46909	7590	01/12/2005		
TERUMO CARDIOVASCULAR SYSTEMS CORPORATION 6200 JACKSON ROAD ANN ARBOR, MI 48103			EXAMINER DESANTO, MATTHEW F	
			ART UNIT 3763	PAPER NUMBER

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,098

Applicant(s)

GERSHOWITZ, ARTHUR D.

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Newly submitted claim 23 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 23 is drawn to a non-elected species.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 23 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 4-6, 18 – 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Dye et al. (USPN 3,742,960)

Dye et al. discloses a retrograde cannula comprising a body with a proximal and distal end, and an infusion lumen (28) extending there between, with an infusion port (24), an automatically inflatable balloon, a valve (60) arranged in the body and a drainage lumen (32), wherein the passage arrangement constitutes the sole means of delivering inflation fluid to the balloon (Figures 1, and entire reference, Column 3, lines 26-40).

2. Claims 1, 4-6, 18, and 19 - 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Lafontaine et al. (USPN 5,695,468).

Lafontaine et al. discloses a retrograde cannula comprising a body with a proximal and distal end, and an infusion lumen (42) extending there between, with an infusion port, an automatically inflatable balloon, a valve (51) arranged in the body and a drainage lumen (18, 47b), wherein the passage arrangement constitutes the sole means of delivering inflation fluid to the balloon (Col. 10, line 1 – Col. 12, line 30).

3. Claims 1, 4-6, and 18 – 23 are rejected under 35 U.S.C. 102(b) as being anticipated by DiCaprio et al. (USPN 6,176,843)

DiCaprio et al. discloses a retrograde cannula comprising a body with a proximal and distal end, and an infusion lumen (32) extending there between, with an infusion port (38), an automatically inflatable balloon, a valve (34) arranged in the body and a drainage lumen (28), wherein the passage arrangement constitutes the sole means of delivering inflation fluid to the balloon (Column 4, line 31 – Column 5, line 60).

Response to Arguments

4. Applicant's arguments, filed 10/19/04, with respect to Finney have been fully considered and are persuasive. The 102 Rejection of Finney has been withdrawn.

5. Applicant's arguments filed 10/19/04 have been fully considered but they are not persuasive, with regards to Dye et al., Lafontaine et al. and DiCaprio et al.

6. The applicant argues intended use and functional language for the reason of patentability over Dye et al., Lafontaine et al. and DiCaprio et al. The examiner notes section 2114 of the MPEP, which states, "that an apparatus must be distinguished from

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the prior art in terms of structure rather than function. >In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997)." Dye et al., Lafontaine et al. and DiCaprio et al. have the same structure of that is claimed and therefore the examiner determines that each prior art reference would be capable of performing the intended use and functional language that is claimed if the examiner interpretation is given to each prior art reference. Therefore, the examiner maintains his rejections.

7. The examiner further uses case law to support his interpretation of the prior art. In response to applicant's argument that of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto
Art Unit 3763
January 5, 2005



NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700